treatment. Despite being recognized as the gold standard of care that can cut the risk of overdose in half, only about 1 in 10 individuals with opioid use disorder received medications like buprenorphine to treat their addiction. That is a glaring systemic failure.

H.R. 7666 takes a strong step to address that failure by expanding access to safe and effective addiction treatment through eliminating the outdated and redundant requirement that healthcare providers obtain a special waiver from the DEA to prescribe buprenorphine for the treatment of addiction.

Despite the lifesaving potential this legislation can bring, this amendment raises concerns about the impact the MAT Act will have on safety, abuse, and diversion, and I would take a moment to directly address these concerns.

Let's start with the basic facts on safety.

Unlike heroin and fentanyl that are causing overdose deaths, buprenorphine is a safe medication that is highly effective at protecting people from overdose.

Due to its ceiling effect, buprenorphine does not cause people to feel high and is unlikely to result in substance use disorder or be a cause of overdose deaths.

With regard to diversion and abuse, the DEA, which is responsible for policing illicit diversion, has specifically looked at this issue and found that the primary reason for buprenorphine diversion is the failure to access legitimate treatment, and that increasing, not limiting, buprenorphine treatment may be an effective response to diversion.

Indeed, as buprenorphine access has increased over the last 5 years through legislation passed by this Congress, misuse of the medication has decreased.

So I would say that it is important for us to be responsible here. We are in the midst of a pandemic, an epidemic that is causing great pain, great suffering, great death, every day, every week. Every moment we circumvent our responsibilities, someone is paying the price for that.

Madam Speaker, I strongly oppose this amendment.

Mr. PALLONE. Madam Speaker, I yield back the balance of my time.

Mr. GRIFFITH. Madam Speaker, I yield 1 minute to the gentlewoman from Washington (Mrs. RODGERS).

Mrs. RODGERS of Washington. Madam Speaker, I appreciate the gentleman for yielding.

Madam Speaker, I rise in support of the Griffith amendment which provides additional time for implementation of the provisions of the Mainstreaming Addiction Treatment Act included in this bill.

I supported the inclusion of this language at committee, as I believe it will help increase access to substance use disorder treatment, the underlying language. However, enacting this language will be a huge policy change from the status quo.

Furthermore, States do regulate the practice of medicine, and each State has unique, individual regulations and procedures regarding the dispensing and the prescribing of scheduled narcotics. States could use the additional time to update their laws with any changes they may want now that Federal restrictions will be removed.

This is exactly what Mr. GRIFFITH's amendment does. It sets the implementation date for removing the X waiver requirement to take effective on January 1, 2024.

Madam Speaker, I support this commonsense amendment that will ensure that the Mainstreaming Addiction Treatment Act gets appropriately implemented.

Mr. GRIFFITH. Madam Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. Pursuant to House Resolution Number 1191, the previous question is ordered on the amendment offered by the gentleman from Virginia (Mr. GRIFFITH).

The question is on the amendment.

The question was taken; and the Speaker pro tempore announced that the noes appeared to have it.

Mr. GRIFFITH. Madam Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this question are postponed.

Pursuant to clause 1(c) of rule XIX, further consideration of H.R. 7666 is postponed.

ADVANCED RESEARCH PROJECTS AGENCY-HEALTH ACT

Mr. PALLONE. Mr. Speaker, pursuant to House Resolution 1191, I call up the bill (H.R. 5595) to establish the Advanced Research Projects Agency-Health, and for other purposes, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore (Mr. CARSON). Pursuant to House Resolution 1191, the amendment in the nature of a substitute recommended by the Committee on Energy and Commerce printed in the bill is adopted, and the bill, as amended, is considered read.

The text of the bill, as amended, is as follows:

H.R. 5585

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Advanced Research Projects Agency–Health Act'' or the ''ARPA–H Act''.

SEC. 2. ADVANCED RESEARCH PROJECTS AGENCY–HEALTH.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

''PART J—ADVANCED RESEARCH PROJECTS AGENCY–HEALTH

''SEC. 499A. ADVANCED RESEARCH PROJECTS AGENCY–HEALTH.

''(a) ESTABLISHMENT.—There is established, as an independent operating division within the Department of Health and Human Services, the Advanced Research Projects Agency–Health (in this part referred to as 'ARPA–H'). Not later than 180 days after the date of enactment of this part, the Secretary shall transfer all functions, personnel, missions, activities, authorities, and funds of the Advanced Research Projects Agency for Health within the National Institutes of Health, as in existence on the date of enactment of this part, to ARPA–H established by the preceding sentence.

''(b) GOALS AND METHODS.—

''(1) GOALS.—The goals of ARPA–H shall be to—

''(A) foster the development of new, breakthrough capabilities, technologies, systems, and platforms to accelerate innovations in health and medicine that are not being met by Federal programs or private entities;

''(B) revolutionize detection, diagnosis, mitigation, prevention, treatment, and curing of serious diseases and medical conditions through the development of transformative health technologies;

''(C) promote high-risk, high-reward innovation for the development and translation of transformative health technologies; and

''(D) contribute to ensuring the United States maintains—

''(i) global leadership in science and innovation;

''(ii) the highest quality of life and health for its citizens; and

''(iii) an aggressive agenda for innovations to address global health threats that place United States citizens at risk.

''(2) METHODS.—ARPA–H shall achieve the goals specified in paragraph (1) by—

''(A) discovering, identifying, and promoting revolutionary advances in health sciences;

''(B) translating scientific discoveries into transformative health technologies;

''(C) providing resources and support to create platform capabilities that draw on multiple disciplines;

''(D) using researchers in a wide range of disciplines, including the life sciences, the physical sciences, engineering, and the computational sciences;

''(E) delivering advanced proofs of concept that demonstrate potentially clinically meaningful advances;

''(F) developing new capabilities, advanced computational tools, predictive models, or analytical techniques to identify potential targets and technological strategies for early disease detection and intervention;

''(G) accelerating transformational technological advances in areas with limited technical certainty; and

''(H) prioritizing investments based on such considerations as—

''(i) scientific opportunity and uniqueness of fit to the strategies and operating practices of ARPA–H;

''(ii) the effect on disease burden, including unmet patient need, quality and disparity gaps, and the potential to preempt progression of serious disease; and

''(iii) the effect on the fiscal liability of the Federal Government with respect to health care and the ability to reduce the cost of care through innovation.

''(c) DIRECTOR.—

''(1) IN GENERAL.—The President shall appoint with the advice and consent of the Senate, a director of ARPA–H (in this part referred to as the 'Director').

''(2) QUALIFICATIONS.—The Director shall be an individual who, by reason of professional background and experience, is especially qualified to manage—

''(A) research and advanced development programs; and

''(B) large-scale, high-risk initiatives with respect to health research and technology development across multiple sectors, including generating transformative health technologies and improving health outcomes for patients.

''(3) RELATIONSHIP TO SECRETARY.—The Director shall report directly to the Secretary.

''(4) DUTIES.—The duties of the Director shall include the following:

''(A) Approve and terminate the projects and programs of ARPA–H.

''(B) Set research and development priorities with respect to the goals specified in subsection (b) and manage the budget of ARPA–H.

''(C) Develop funding criteria and assess the success of programs through the establishment of technical milestones.

''(D) Advance the goals under subsection (b), through consideration of the advice of the ARPA–H Interagency Research Council established under subsection (q).

''(E) Solicit data, as needed, from the National Institutes of Health and other relevant entities.

''(F) Coordinate with the Director of the National Institutes of Health to ensure that the programs of ARPA–H build on, and are informed by, scientific research supported by the National Institutes of Health.

''(G) Coordinate with the heads of Federal agencies and, to the extent practicable, ensure that the activities of ARPA–H supplement (and do not supplant) the efforts of other Federal agencies.

''(H) Ensure ARPA–H does not provide funding for a project unless the program manager determines that the project meets the goals described in subsection (b)(1).

''(5) TERM.—The Director—

''(A) shall be appointed for a 5-year term; and

''(B) may be reappointed for 1 consecutive 5-year term.

''(6) AUTONOMY OF AGENCY REGARDING RECOMMENDATIONS AND TESTIMONY.—No officer or agency of the United States shall have any authority to require the Director or any other officer of ARPA–H to submit legislative recommendations, or testimony or comments on legislation, to any officer or agency of the United States for approval, comments, or review prior to the submission of such recommendations, testimony, or comments to the Congress, if such recommendations, testimony, or comments to the Congress include a statement indicating that the views expressed therein are those of the Director or such officer, and do not necessarily reflect the views of the President or another agency.

''(7) DELEGATION OF AUTHORITY.—The Director may delegate to any duly authorized employee, representative, or agent any power vested in the Director by law, except that the Director may not delegate the power to appoint the Deputy Director under paragraph (8).

''(8) DEPUTY DIRECTOR.—The Director shall appoint a deputy director to serve as the first assistant to the office.

''(d) APPLICATION OF PAPERWORK REDUCTION ACT.—The Director may waive the requirements of subchapter I of chapter 35 of title 44, United States Code (commonly referred to as the 'Paperwork Reduction Act') with respect to the methods described in subsection (b)(2).

''(e) PROTECTION OF INFORMATION.—The following types of information collected by ARPA–H from recipients of financial assistance awards shall be considered commercial and financial information obtained from a person and privileged or confidential and not subject to disclosure under section 552(b)(4) of title 5, United States Code:

''(1) Plans for commercialization of technologies developed under the award, including business plans, technology-to market plans, market studies, and cost and performance models.

''(2) Investments provided to an awardee from third parties (such as venture capital firms, hedge funds, and private equity firms), including amounts and the percentage of ownership of the awardee provided in return for the investments.

''(3) Additional financial support that the awardee—

''(A) plans to invest or has invested in the technology developed under the award; or

''(B) is seeking from third parties.

''(4) Revenue from the licensing or sale of new products or services resulting from research conducted under the award.

''(f) SHARING INFORMATION WITH THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—The Director shall timely share relevant information with the Administrator of the Centers for Medicare & Medicaid Services that may help to expedite determinations of coverage of transformative health technologies developed by ARPA–H.

''(g) EXPEDITING BREAKTHROUGHS THROUGH COOPERATION WITH THE FOOD AND DRUG ADMINISTRATION.—

''(1) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Director, may take actions to facilitate translation of transformative health technology into tangible solutions for patients and to expedite development of drugs, devices, and biological products, including through—

''(A) helping to ensure that drug, device, or biological product development programs, in as efficient a manner as possible, gather the nonclinical and clinical data necessary to advancing the development of such products and to obtaining their approval, licensure, or clearance, as applicable, by the Food and Drug Administration under sections 505, 510(k), and 515 of the Federal Food, Drug, and Cosmetic Act and section 351 of this Act;

''(B) expediting review of investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act, review of investigational device exemptions under section 520(g) of such Act, and review of applications for approval, licensure, and clearance of drugs, devices, or biological products under sections 505, 510(k), and 515 of such Act, and section 351 of this Act; and

''(C) meeting at appropriate intervals with the Director and any member of the ARPA–H Interagency Research Council to discuss the development status of drugs, devices, or biological products and projects that are the highest priorities to ARPA–H, unless the Director and the Commissioner of Food and Drugs determine that any such meetings are not necessary.

''(2) RELATION TO OTHERWISE AUTHORIZED ACTIVITIES OF THE FDA.—The authority specified in paragraph (1) shall not be construed as limiting the authority of the Secretary, acting through the Commissioner of Food and Drugs, with respect to the review and approval, clearance, authorization for emergency use, or licensure of drugs, devices, or biological products under the Federal Food, Drug, and Cosmetic Act or section 351 of this Act.

''(3) REIMBURSEMENT.—The Director, using funds made available to ARPA–H, may reimburse the Food and Drug Administration for expenditures made by the Food and Drug Administration for activities carried out under this section that have been identified by the Commissioner of Food and Drugs and the Director as being carried out by the Food and Drug Administration.

''(h) AWARDS.—

''(1) IN GENERAL.—In carrying out this section, the Director may make awards including—

''(A) grants and cooperative agreements, which shall—

''(i) be subject to the uniform administrative requirements, cost principles, and audit requirements for Federal awards contained in part 200 of title 2, Code of Federal Regulations (or successor regulations); and

''(ii) include the total line-item and itemized indirect facilities and administrative costs that shall be made publicly available and published in a machine-readable format;

''(B) contracts subject to the Federal Acquisition Regulation;

''(C) multi-year contracts under section 3903 of title 41, United States Code;

''(D) prizes; and

''(E) other transactions.

''(2) EXEMPTIONS FOR CERTAIN REQUIREMENTS.—Research funded by ARPA–H shall not be subject to the requirements of section 406(a)(3)(A)(ii) or section 492.

''(i) FACILITIES AUTHORITY.—

''(1) IN GENERAL.—The Director may acquire (by purchase, lease, condemnation, or otherwise), construct, improve, repair, operate, and maintain such real and personal property as may be necessary to carry out this section.

''(2) LEASE OF NONEXCESS PROPERTY.—The Director may enter into a lease under this section with any person or entity (including another department or agency of the Federal Government or an entity of a State or local government) with regard to any nonexcess real property and related personal property under the jurisdiction of the Director.

''(3) UTILIZATION OF LEASE FUNDS.—

''(A) IN GENERAL.—The Director may utilize, without further appropriation, amounts of cash consideration received for a lease entered into under this subsection to cover the full costs to ARPA–H in connection with the lease. Funds received as such cash consideration shall remain available until expended.

''(B) CAPITAL REVITALIZATION AND IMPROVEMENTS.—Of any amounts of cash consideration received under this subsection that are not utilized in accordance with subparagraph (A), without further appropriation—

''(i) 35 percent shall—

''(I) be deposited in a capital asset account to be established by the Director;

''(II) be available for maintenance, capital revitalization, and improvements of the real property assets and related personal property under the jurisdiction of the Director; and

''(III) remain available until expended; and

''(ii) the remaining 65 percent shall be available to the respective center or facility of ARPA–H engaged in the lease of nonexcess real property, and shall remain available until expended for maintenance, capital revitalization, and improvements of the real property assets and related personal property at the respective center or facility subject to the concurrence of the Director.

''(C) NO UTILIZATION FOR DAILY OPERATING COSTS.—Amounts utilized under subparagraph (B) may not be utilized for daily operating costs.

''(4) LOCATIONS.—

''(A) IN GENERAL.—ARPA–H, including its headquarters, shall not be located on any part of the existing National Institutes of Health campuses.

''(B) CONSIDERATIONS.—In determining the location of facilities, the Director shall make a fair and open consideration of—

''(i) the characteristics of the intended location; and

''(ii) the extent to which such location will facilitate advancement of the goals and methods specified in subsection (b).

''(j) PERSONNEL.—

''(1) IN GENERAL.—The Director may—

''(A) make and rescind appointments of scientific, engineering, medical, and professional personnel, which may include temporary or time-limited appointments as determined by the Director to fulfill the mission of ARPA–H, without regard to any provision in title 5, United States Code, governing appointments and removals under the civil service laws, and fix the base pay compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code; and

''(B) contract with private recruiting firms for the hiring of qualified staff referenced in subparagraph (A).

''(2) ADDITIONAL STAFF.—The Director may use, to the same extent and in the same manner as the Secretary, all authorities in existence on the date of the enactment of this section that are provided to the Secretary to hire administrative, financial, contracts, legislative affairs, information technology, ethics, and communications staff, and such other staff as may be identified by the Director as necessary to carry out this section.

''(3) ADDITIONAL CONSIDERATIONS.—In appointing personnel under this subsection, the Director—

''(A) may contract with private entities;

''(B) shall make efforts to recruit and retain a diverse workforce, including individuals underrepresented in science and medicine and racial and ethnic minorities (as long as such efforts comply with applicable Federal civil rights law); and

''(C) shall recruit program managers with expertise in a wide range of relevant disciplines, including life sciences, the physical sciences, engineering, and the computational sciences.

''(4) ADDITIONAL HIRING AUTHORITY.—To the extent needed to carry out the authorities vested by paragraph (1), the Director may utilize hiring authorities under sections 3371 through 3376 of title 5, United States Code, to staff ARPA–H with employees from other Federal agencies, State and local governments, Indian Tribes and Tribal organizations, institutions of higher education, and other organizations, as described in such sections.

''(5) EXISTING AUTHORITIES.—The authorities granted by this section are—

''(A) in addition to existing authorities granted to the Secretary; and

''(B) are not intended to supersede or modify any existing authorities.

''(6) AUTHORITY TO ACCEPT FEDERAL DETAILEES.—The Director may accept officers or employees of the United States or members of the uniformed service on a detail from an element of the Federal Government on a reimbursable or a nonreimbursable basis, as jointly agreed to by the heads of the receiving and detailing elements, for a period not to exceed 3 years.

''(k) PROGRAM MANAGERS.—

''(1) IN GENERAL.—The Director shall appoint program managers for 3-year terms (and may reappoint such program managers for 1 consecutive 3-year term) for the programs carried out by ARPA–H.

''(2) DUTIES.—A program manager shall—

''(A) establish, in consultation with the Director or Deputy Director, research and development goals for programs, including timelines and milestones, and make such goals available to the public;

''(B) collaborate with experts from the National Institutes of Health and other Federal agencies and experts in relevant scientific fields to identify research and development gaps and opportunities;

''(C) convene workshops and meetings, as needed, with entities such as patients, patient advocacy groups, practitioners, professional societies, and other stakeholders to solicit input on programs and goals;

''(D) manage applications and proposals, through the appropriate officials for making grants, cooperative agreements, contracts, prizes, and other transaction awards for advanced research that may show particular promise, especially in areas in which the private sector and the Federal Government have not undertaken sufficient research;

''(E) issue funding opportunity announcements, using uniform administrative processes, as appropriate;

''(F) select, on the basis of merit, each of the projects to be supported under a program carried out by ARPA–H, and taking into consideration—

''(i) the scientific and technical merit of the proposed project;

''(ii) the capabilities of the applicants to successfully carry out the proposed project;

''(iii) the unmet needs or ability to improve health outcomes within patient populations;

''(iv) future commercial applications of the project or the feasibility of partnering with one or more commercial entities;

''(v) the potential for interdisciplinarity of the approach of the project; and

''(vi) such other criteria as established by the Director;

''(G) conduct project reviews within 18 months of funding awards to identify milestones and monitor progress of such milestones with respect to each project and prior to disbursement of new funds;

''(H) provide recommendations to the Director with respect to advancing the goals specified in subsection (b);

''(I) cultivate opportunities for the commercial application or community use of successful projects, including through the establishment of partnerships between or among awardees;

''(J) identify innovative cost-sharing arrangements for ARPA–H projects;

''(K) provide recommendations to expand, restructure, or terminate research partnerships or projects; and

''(L) ensure that—

''(i) animal studies meet the Federal animal research requirements pursuant of the Public Health Service Policy on Humane Care and Use of Laboratory Animals; and

''(ii) applications apply statistical modeling approaches and appropriately justify animal sample sizes to meet project goals.

''(l) REPORTS AND EVALUATION.—

''(1) ANNUAL REPORT.—

''(A) IN GENERAL.—Beginning not later than 1 year after the date of enactment of this section, and each fiscal year thereafter, the Director shall submit a report on the actions undertaken, and results generated, by ARPA–H, including—

''(i) a description of projects supported by ARPA–H in the previous fiscal year and whether such projects are meeting the goals developed by the Director pursuant to subsection (c)(4)(C);

''(ii) a description of projects terminated in the previous fiscal year, and the reason for such termination;

''(iii) a description of programs starting in the next fiscal year, as available;

''(iv) activities conducted in coordination with other Federal agencies;

''(v) an analysis of the extent of coordination conducted pursuant to subsections (c)(4)(F) and (f), including successes and barriers with respect to achieving the goals under subsection (b);

''(vi) a description of the demographic (including racial and gender) diversity if available of direct recipients and performers in funded projects and of the ARPA–H workforce; and

''(vii) a disclosure by the reward recipients of whether the principal investigators named on the award participate in foreign talent programs, including the provision of copies of all grants, contracts, or other agreements related to such programs, and other supporting documentation related to such programs, as a condition of receipt of Federal extramural biomedical research funding awarded.

''(B) SUBMISSION TO CONGRESS.—The report under subparagraph (A) shall be submitted to—

''(i) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives; and

''(ii) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate.

''(2) EVALUATION.—

''(A) IN GENERAL.—Not later than 5 years after the date of the enactment of this section, the Secretary shall enter into an agreement with the National Academies of Sciences, Engineering, and Medicine under which the National Academies agree to study and evaluate whether ARPA–H is meeting the goals specified in subsection (b).

''(B) SUBMISSION OF RESULTS.—The agreement entered into under subparagraph (A) shall require the National Academies of Sciences, Engineering, and Medicine to submit the results of the evaluation conducted under such agreement to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

''(m) STRATEGIC PLAN.—Not later than 1 year after the date of the enactment of this section, and every 3 years thereafter, the Director shall provide to the relevant committees of Congress a strategic plan describing how ARPA–H will carry out investments each fiscal year in the following 3-year period.

''(n) INDEPENDENT REVIEW.—Not later than 1 year after the date of the enactment of this section, and every 3 years thereafter, the Comptroller General of the United States shall conduct an independent review of the research portfolio of the Department of Health and Human Services, including ARPA–H, the National Institutes of Health, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority—

''(1) to assess the degree of unnecessary duplication of existing Federal programs and projects; and

''(2) to make recommendations regarding any potential reorganization, consolidation, or termination of such programs and projects.

''(o) PRIORITIZATION.—The Director shall—

''(1) prioritize awarding grants, cooperative agreements, contracts, prizes, and other transaction awards to domestic recipients conducting the research on transformative health technology in the United States;

''(2) as appropriate and practicable, ensure that nondomestic recipients of any grants, cooperative agreements, contracts, prizes, and other transactions under this section are conducting research in collaboration with a domestic recipient;

''(3) not award any grants, cooperative agreements, contracts, prizes, and other transactions to nondomestic recipients subject to malign foreign influence or organized under the laws of a malign foreign country; and

''(4) in accordance with the requirements of chapter 33 of title 41, United States Code, and the Federal Acquisition Regulation, only award grants, cooperative agreements, contracts, prizes, and other transactions to individual persons that do not have more than 3 ongoing concurrent grants, cooperative agreements, contracts, prizes, and other transactions under this section.

''(p) ADDITIONAL CONSULTATION.—In carrying out this section, the Director may consult with—

''(1) the President's Council of Advisors on Science and Technology;

''(2) peers in the scientific community, including academia and industry;

''(3) an existing advisory committee providing advice to the Secretary or the head of any operating or staff division of the Department;

''(4) a new interagency research council organized to support the programs of ARPA–H and to provide advice and assistance on—

''(A) specific program tasks; or

''(B) the overall direction of ARPA–H; and

''(5) any other entity the Director may deem appropriate.

''(q) ARPA–H INTERAGENCY RESEARCH COUNCIL.—

''(1) IN GENERAL.—The Director shall establish an interagency advisory committee to be known as the ARPA–H Interagency Research Council (referred to in this subsection as the 'Research Council').

''(2) MEMBERSHIP.—The Research Council may include any or all of the following members, or designees:

''(A) The Director of the National Institutes of Health.

''(B) The Director of National Center for Advancing Translational Sciences.

''(C) The Director of Office of Science and Technology Policy.

''(D) The Commissioner of Food and Drugs.

''(E) The Director of the Biomedical Advanced Research and Development Authority.

''(F) The Director of the Centers for Disease Control and Prevention.

''(G) The Administrator of the Centers for Medicare & Medicaid Services.

''(H) The Director of the Agency for Healthcare Research and Quality.

''(I) The Director of the Office of Minority Health.

''(J) The Administrator of the Health Resources and Services Administration.

''(K) The Director of the Defense Advanced Research Projects Agency.

''(L) The Director of the National Science Foundation.

''(M) The Director of the Office of Science of the Department of Energy.

''(N) The Director of the Advanced Research Projects Agency–Energy.

''(O) The Assistant Secretary for Preparedness and Response.

''(P) Representatives of any Federal agency with subject matter expertise that the Director determines is necessary for the successful completion of a project carried out pursuant to this section.

''(Q) Any other entity the Director may deem appropriate.

''(3) DUTIES.—The Research Council shall advise the Director, including by—

''(A) making recommendations on—

''(i) research priorities that will provide the greatest return on investment with respect to improving human health;

''(ii) avoiding duplication of efforts in the Federal Government; and

''(iii) improving coordination with other Federal agencies; and

''(B) identifying and developing strategies to address regulatory, reimbursement, and market barriers to commercialization or adoption of transformative health technologies, including technologies intended to preempt serious disease.

''(4) ADVISORY NATURE.—The function of the Research Council shall be advisory in nature. Nothing in this subsection shall be construed as granting the Research Council authority over any activities or functions of ARPA–H.

''(5) MEETINGS.—Not later than 1 year after the date of the enactment of this section, and every fiscal year thereafter, the Director shall convene meetings of the Research Council, including conferences or workshops, as needed. The Research Council may function through established or ad hoc committees, task forces, or interagency groups to—

''(A) share information on health innovations funded by ARPA–H; and

''(B) receive input on areas of particular promise for ARPA–H projects.

''(r) TECHNOLOGY TRANSFER OFFICE.—The Director may establish within ARPA–H an Office of Technology Transfer to facilitate, where appropriate, the transfer of federally-owned or federally-originated technology to recipients of an award under this section (other than Federal Government entities).

''(s) FOLLOW-ON PRODUCTION AWARD AUTHORITY.—

''(1) IN GENERAL.—An other transaction entered into by the Director under subsection (h)(1) for a project may provide for the award of a follow-on production contract or transaction to the participants in the transaction by ARPA–H or another Federal agency. For purposes of this paragraph, such an other transaction includes all individual subprojects awarded under the transaction to a consortium of United States industry and academic institutions.

''(2) RELATION TO COMPETITIVE PROCEDURES.—A follow-on production contract or transaction under paragraph (1) may be awarded to the participants in the transaction without the use of competitive procedures (as defined in section 152 of title 41, United States Code), notwithstanding the requirements of division C of subtitle I of such title 41, if—

''(A) competitive procedures were used for the selection of parties for participation in the other transaction; and

''(B) the participants in the other transaction successfully completed the project provided for in the transaction.

''(3) PRECONDITION.—A follow-on production contract or transaction may be awarded pursuant to this subsection when the Director determines that an individual project or subproject as part of a consortium is successfully completed by the participants.

''(4) CLARIFICATION.—Award of a follow-on production contract or transaction pursuant to this subsection shall not be made contingent upon the successful completion of all activities within a consortium as a condition for an award for follow-on production of a successfully completed project or subproject within that consortium.

''(5) OTHER AUTHORITIES.—Contracts and transactions entered into by ARPA–H pursuant to this subsection may be awarded pursuant to division C of subtitle I of title 41, United States Code, or under such procedures, terms, and conditions as the Director or head of such agency may establish by regulation.

''(t) RULE OF CONSTRUCTION.—The authorities under this section, with respect to the Director, are additional authorities that do not supersede or modify any existing authorities.

''(u) DEFINITIONS.—In this part:

''(1) ADVANCED PROOFS OF CONCEPT.—The term 'advanced proofs of concept' means data, a prototype, or other experimental evidence that—

''(A) may precede the development of transformative health technologies; and

''(B) demonstrates the feasibility of a new concept.

''(2) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 351(i).

''(3) DEPARTMENT.—The term 'Department' means the Department of Health and Human Services.

''(4) DRUG; DEVICE.—The terms 'drug' and 'device' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.

''(5) FEDERAL ACQUISITION REGULATION.—The term 'Federal Acquisition Regulation' means the Federal Acquisition Regulation issued pursuant to section 1303(a)(1) of title 41, United States Code.

''(6) FEDERAL AGENCY.—The term 'Federal agency' has the meaning given such term in section 3371 of title 5, United States Code.

''(7) PRIZE.—The term 'prize' means a prize as such term is used in section 24 of the Stevenson-Wydler Technology Innovation Act of 1980.

''(8) TRANSFORMATIVE HEALTH TECHNOLOGY.—The term 'transformative health technology' means a drug, biological product, intervention, platform, tool, or device—

''(A) that should be prioritized to detect, diagnose, mitigate, prevent, cure, or treat a serious disease or medical condition for which there are unmet needs; and

''(B) for which—

''(i) significant scientific uncertainty and regulatory risk exist; or

''(ii) incentives in the commercial market are unlikely to result in the adequate or timely development of such drug, biological product, intervention, platform, tool, or device.

''(v) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $500,000,000 for each of fiscal years 2023 through 2027, to remain available until expended.''.

The SPEAKER pro tempore. The bill, as amended, shall be debatable for 1 hour equally divided and controlled by the Chair and ranking minority member of the Committee on Energy and Commerce or their respective designees.

After 1 hour of debate, it shall be in order to consider the further amendment printed in part C of House Report 117–381, if offered by the Member designated in the report, which shall be considered read, shall be separately debatable for the time specified in the report equally divided and controlled by the proponent and an opponent, and shall not be subject to a demand for a division of the question.

The gentleman from New Jersey (Mr. PALLONE), and the gentleman from Kentucky (Mr. GUTHRIE), each will control 30 minutes.

The Chair recognizes the gentleman from New Jersey (Mr. PALLONE).

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include any extraneous material on H.R. 5585.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise to speak in support of H.R. 5585, the Advance Research Projects Agency–Health Act, or ARPA–H Act.

In February, the Energy and Commerce Committee's Health Subcommittee held a hearing to discuss the Biden administration's proposal to establish the Advance Research Projects Agency for Health, better known as ARPA–H.

The agency is modeled after the Defense Advanced Research Projects Agency, or DARPA. The mission of ARPA–H is to translate fundamental biomedical research into breakthrough platform technologies that would change healthcare as we know it.

ARPA–H would focus on the highest-risk, highest-reward issues in disease research. It will attempt to solve the problems that the private and public sectors have not been able to conquer. The expectations we have for this agency are justifiably high.

Our hope is that within 5 years of operations, ARPA–H will have led to the development of cutting-edge treatments and cures for cancer, diabetes, autoimmune disorders, and mental health conditions.

In order to be truly successful, we must ensure that all Americans have access to these innovations. Equity and promoting the health of all Americans must also be part of ARPA–H's mission.

The fiscal year 2022 omnibus appropriations law provided the Department of Health and Human Services with $1 billion to get ARPA–H off the ground. We must now provide the necessary and appropriate authorities to make ARPA–H successful, to clarify its mission and its organizational structure,

and ensure that the work at ARPA–H is not duplicative or redundant. H.R. 5585 does just that.

ARPA–H will be led by a director and cadre of program managers with the autonomy and authority to develop high-risk, high-reward portfolios. This will be coupled with the appropriate contracting, hiring, and procurement authorities that will pull from the best minds and resources in the biomedical research ecosystem.

This legislation authorizes $500 million annually for 5 fiscal years. ARPA–H projects will be time- and milestone-limited, ensuring that each project delivers real and measurable results. The ARPA–H Act includes reporting requirements to ensure proper compliance and avoid the redundancy. The director will be required to submit reports on the actions, results, and forthcoming strategic plans of ARPA–H to Congress so that we can confirm that the agency is meeting our intent.

So last month, the Committee on Energy and Commerce advanced H.R. 5585 by an overwhelming bipartisan vote of 55–3. This was a tremendous achievement and demonstrates Congress' ability to come together and find solutions that will improve the health of all Americans.

I thank Health Subcommittee Chairwoman ESHOO, who is the author of this legislation, along with Health Subcommittee Ranking Member GUTHRIE, our full committee Ranking Member RODGERS, and also Representatives DeGette and Upton for their work on this important bill.

Mr. Speaker, I strongly urge my colleagues to support H.R. 5585, and I reserve the balance of my time.

Mr. GUTHRIE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise to speak in support of the Advanced Research Projects Agency-Health Act, or ARPA–H Act. I know this has been an important priority for researchers, industry, and, most importantly, patients who are waiting for life-changing medical technology to improve or even save their lives.

This legislation will authorize the establishment of ARPA–H within the U.S. Department of Health and Human Services. The agency will specifically be charged with helping to foster high-risk, high-reward treatments and cures for diseases with clinically unmet needs.

Some of my colleagues may be concerned about a new agency, and that is where a number of Republicans on the Committee on Energy and Commerce were early in October when this legislation was introduced.

ARPA–H was funded at $1 billion in the previous appropriations bill in 2021. To ensure that funding was used for the best possible result, the Committee on Energy and Commerce for the past several months has worked hard to ensure that ARPA–H has a clear mission. As a result, it passed out of committee with a strong 55-to-3 vote.

□ 1615

We most notably ensure this newly created agency remains separate from the NIH. We limit administration costs associated with setting up ARPA–H to maximize research investments, which would require a strategic plan and transparent reporting on projects; define the number of offices; and require that the majority of offices within the organization be exclusively devoted to biomedical research and development.

In order to ensure this agency is fostering the development of innovative, transformative health technologies that are not being met by Federal programs or private industry, the technologies the agency should pursue are very explicitly defined in the legislation before us today.

The legislation puts guardrails in place to ensure that priority access is granted to U.S. researchers over researchers abroad. There are additional requirements for international researchers to work in collaboration with a U.S. counterpart if they receive ARPA–H funding.

Importantly, the bill makes clear that funding is prohibited from going to nondomestic recipients of a malign foreign country, most notably Chinese research labs or Russian research labs. This is a significant step to ensure the United States' intellectual property isn't being stolen by our adversaries and to ensure we remain the world leader in biomedical research and innovation.

As the Republican leader on the Health Subcommittee, I am leading efforts to strengthen oversight of NIH-funded research. It is unacceptable that some Federal grants have been supporting foreign researchers with ties to governments of adversarial nations like China. We must prevent this from happening moving forward.

Mr. Speaker, I emphasize the need to pass this bill. The funding has already been appropriated in a previous year. If we don't pass this bill and don't authorize this agency to move forward, then this will erode our oversight role in Congress. Funding decisions made by ARPA–H must require diligence to ensure that resources are being spent as appropriately and as effectively as possible.

The Biden administration ARPA–H organizational chart, without this bill, has 14 offices, less than half of which are actually dedicated to research. This gives us insight into how the Biden administration would manage this new agency without congressional guidance. It is just appropriate that the legislative branch sets up the way this money is being spent.

That is what the bill before us today does. It puts ARPA–H on the right track, gives Congress the opportunity to set high standards, and promotes greater biomedical research and innovation for patients.

Mr. Speaker, I thank the majority for working together. I thank our staff for the excellent work they have done. I encourage the passage of this because if we don't pass it, the money is still going to be spent but without congressional guardrails.

Mr. Speaker, I support this bill, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentlewoman from California (Ms. ESHOO), the Health Subcommittee chair and the author of this legislation.

Ms. ESHOO. Mr. Speaker, I thank the chairman of the full committee for his full support of this legislation from the very beginning.

Mr. Speaker, this has been somewhat of a long journey. It began in March of last year, 2021, when a group of Members, bipartisan and bicameral, were invited to the White House to meet with President Biden. When we gathered there, he spoke about his vision for creating ARPA–H, an advanced research project for health.

It is modeled after DARPA, the highly innovative and successful small agency that was created many years ago. I think one of its chief assets is its autonomy, and its successes are extraordinary because of the way it is shaped. They have produced the internet, GPS navigation, and Moderna's mRNA vaccines.

This bill is shaped to maximize the promise of ARPA–H.

All of us have a relative or someone in our family, extended family, and our communities that when receiving a diagnosis, it is a death sentence. That is what the mission of ARPA–H is directed to address. I have full confidence that, the way this legislation is shaped, it can meet that challenge.

It will be a place where highly innovative ideas are tested, and if the approaches fail because these are high-risk undertakings, then the agency will quickly move on to new ones and redirect the money. It will be flat and small like DARPA, but it has a mighty mission.

Mr. Speaker, I thank all the members of the Energy and Commerce Committee on the majority and the minority side. We have really worked hard together on this to shape something that is worthy of the American people and has the ability to produce. From the chairman of the full committee to the ranking member, Mrs. McMorris Rodgers, to the ranking member of the subcommittee, Mr. GUTHRIE, ideas kept coming forward. We polished them, added them to the legislation, and, in some instances, dropped other parts of the draft.

Mr. Speaker, I acknowledge the work of my staffer, Aisling McDonough, who has given her all on this; the staff of the committee; the scientists, because well over 100 of them leaned in and gave us their ideas and advice on how best to create a small agency that would be nimble but highly effective; and the patient advocates. So many of them have cheered us on and given us their best input, as well.

Today is the day. The House is poised. I urge all of my colleagues to

support this because when this mission is executed, I think even if one deadly disease is addressed and cured, we will have succeeded. I think we are going to do better than that.

Mr. GUTHRIE. Mr. Speaker, I yield 5 minutes to the gentlewoman from Washington (Mrs. RODGERS), who is the Republican leader of the full committee.

Mrs. RODGERS of Washington. Mr. Speaker, America is the envy of the world for our leadership in biomedical innovation. People from all over the world have an incredible amount of hope in the promise of our lifesaving, breakthrough research for more cures and treatments.

That is why I have been a longtime supporter of NIH and projects like the BRAIN Initiative intended to speed scientific research necessary to accelerate cures for neurologic diseases.

When the concept of ARPA–H was first proposed to me, I expressed a healthy dose of skepticism.

First, I was concerned about a clear and targeted strategic mission. I was concerned an unfocused agenda would not be a recipe for success.

The second was the issue of duplication. The Federal Government has several agencies that advance biomedical innovation. Within the National Institutes of Health alone, we already have the National Center for Advancing Translational Science, the Cures Acceleration Network, the Common Fund, and the Foundation for NIH's Accelerating Medicines Partnership Program, to name a few.

Third, I was concerned that the creation of a new agency would lack sufficient transparency and oversight. My questions to supporters of ARPA–H included:

How will projects be selected?

How will the public be kept informed of projects and project funding?

Who will be assessing for duplication of Federal programs, and how will it be managed?

What measure will be used to define success?

What are the guardrails to ensure that we are supporting American innovators?

These concerns were validated earlier this year when the administration began implementing the $1 billion that was appropriated to set up ARPA–H with little to no congressional direction. The Biden administration proposed 14 offices within ARPA–H. DARPA has six to eight. They also placed ARPA–H within NIH, which has its own issues in lacking transparency and accountability related to federally funded research and the origins of COVID–19.

We needed to ensure proper oversight and provide guardrails through congressional direction, so we plowed the hard ground necessary to legislate through the Energy and Commerce Committee. Chairman FRANK PALLONE and Health Subcommittee Chairwoman ANNA ESHOO listened to my concerns. We had very productive negotiations to properly define ARPA–H's mission and place strong safeguards for transparency and accountability.

This bill defines ARPA–H's mission so that it is laser-focused on high-risk breakthrough technologies in health and medicine that are not being addressed by the private sector or current Federal programs.

This bill also prohibits Federal funding to China, Russia, and other recipients subject to malign foreign influence.

It moves the agency back outside of NIH.

We are also making sure ARPA–H sets the right priorities. The director must provide Congress with a strategic plan within 1 year of enactment and every 3 years on how ARPA–H will carry out projects. Projects will be evaluated every 18 months, and those not meeting milestones are expected to be terminated.

We placed guardrails on ARPA–H to prioritize projects that provide the greatest return on investment to improve human health and lower healthcare costs.

This bill also keeps the focus on lifesaving research. The director will have the power to hire and make appointments based on merit and expertise, not based on provisions that reward government bureaucrats.

We require those who receive ARPA–H funding to provide a public itemized report on indirect facilities and administrative costs.

To further cut down on duplication and mission creep, we limited the number of offices to 6, not the 14 proposed by the administration. Of those offices, at least four must be exclusively focused on R&D. In addition, not more than 15 percent of the total agency funding is allowed to go to administrative costs.

Mr. Speaker, I will close by thanking my colleagues for working together on this. I especially recognize the leadership of Chairman PALLONE, Health Subcommittee Chairwoman ESHOO, Health Subcommittee Republican leader BRETT GUTHRIE, as well as the 21st Century Cures leaders FRED UPTON and DIANA DEGETTE.

I am pleased we were able to come together. We put ARPA–H on the right path with a targeted mission, increased accountability and transparency, and a laser focus on promoting American innovators. It is a strong example of E&C's bipartisan record of success in moving legislation that will continue America's global leadership in biomedical research.

Mr. Speaker, before I close, I want to applaud and thank the members of my team: Grace Graham, Kristen Shatynski, Seth Gold, Kristin Flukey, and Kristin Ashford.

They say that Energy and Commerce has the best staff on the Hill, and that is certainly evident through their service to deliver hope and healing, both through this bill and through the package just before us with the mental health package. At every step of the way, I am grateful for their hard work and passion.

Mr. Speaker, I urge a ''yes'' vote on H.R. 5585, the Advanced Research Projects Agency-Health Act.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentlewoman from Colorado (Ms. DEGETTE), the chair of our Energy and Commerce Oversight and Investigations Subcommittee who has also worked on ARPA–H in the very beginning.

Ms. DEGETTE. Mr. Speaker, I am so honored to stand here today in support of this legislation, which will revolutionize how our Nation researches and develops new cures and treatments for some of the world's most difficult diseases.

There is not a person in this room or in this Capitol who hasn't been impacted in some way by a devastating disease—cancer, Alzheimer's, or something else. These diseases don't care if you are a Democrat or a Republican. They affect all of us. It needs to be our collective mission to cure all of them immediately.

The ripple effect that they have on our communities is immeasurable. The pain and suffering that they cause, not just to those who become ill but to their families, friends, and loved ones, is irreparable. They place significant strain on our public health systems and significant strain on our economy.

For years, scientists and researchers, both here in the U.S. and around the world, have been searching for ways to prevent and treat these devastating illnesses.

□ 1630

I see my friend and colleague FRED UPTON here on the floor with us today. Fred and I worked on the 21st Century Cures bill in 2016 which has revolutionized the way we do a lot of this discovery and development. But what we need more of now is an all-hands-on-deck approach to end these illnesses, and that is exactly why this legislation was developed.

As Ms. ESHOO, Mr. PALLONE, and others said, it will create a new Advanced Research Projects Agency for Health, ARPA–H, which will bring together some of the world's greatest minds and give them access to the Federal Government's seemingly unlimited resources to make the impossible possible.

Mr. Speaker, modeled after the DARPA program, as you heard, the new agency will be lean and it will be mean. It will be targeted at specifically researching and finding cures for some of the most intractable diseases that we have.

It is going to be run by a small number of program managers, and it will be able to take on the high-risk, high-reward projects that others simply cannot. It will not substitute for the basic research at the NIH or the research at our great universities or in private

business. It will supplement it by targeting these tough issues, and it will reshape the future of biomedical research in this country for many, many years to come.

As I said, this legislation is an opportunity. It is an opportunity to put our country on track to ending cancer as we know it. It is an opportunity to save millions of lives. If we cure cancer, and if we save lives and improve the health and well-being of our constituents, isn't that what we came here for?

Mr. Speaker, I urge everyone to vote ''yes.''

Mr. GUTHRIE. Mr. Speaker, as the chair of this committee, Mr. UPTON made his signature issue the 21st Century Cures, and not just passing that which has changed people's lives already but being able to work with Ms. DEGETTE and all the others to say that this is something we all need to work on together in a bipartisan way and make a big difference.

Now as chair emeritus, this is, I think, his signature piece. He may have other pieces of legislation, too, but this is the one that I have worked on with him in the very beginning in the Oval Office with the President. We worked together to say: Can we do something big that is really going to change the lives of people in this country?

He has done it. He has done it his entire career. He is a mentor of mine, and, unfortunately, at the end of this year he is going to do something different than being here in Congress. He will be missed for his voice and being a champion of this issue.

Mr. Speaker, I am going to yield to him so that he can speak on this bill for himself. The gentleman certainly has left a legacy here with the previous legislation and this piece of legislation. So let's work together to move it forward.

Mr. Speaker, I yield 3 minutes to the gentleman from Michigan (Mr. UPTON).

Mr. UPTON. Mr. Speaker, I thank my very good friend, and I certainly appreciate his kind words. The good news is I am not done yet. We have a lot of work to do, and this is yet one more piece that we are going to be driving forward. But, certainly, I rise in support of this legislation, the ARPA–H authorization bill.

While I have been a longtime supporter of many different versions of this bill, I thank, in particular, Chairman PALLONE, my Republican Leader RODGERS, certainly ANNA ESHOO—who is my good friend—and BRETT GUTHRIE for their leadership on working together on language with the goal of really making this issue bipartisan and one that is going to work.

I am glad that we came together to add even more important guardrails to ensure that this bill, ARPA–H, works as it was intended as well as, hopefully, have a very strong bipartisan vote a little bit later this afternoon.

This bill is going to establish an entity not unlike the Defense Advanced Research Projects entity—that was our goal—DARPA. It is going to be game-changing, health research. Like DARPA, this entity is going to be focused on producing research on things that, frankly, may be too risky for the private sector. It is going to move at a faster pace than the current structure. There may be a high failure rate, but its successes are going to have the potential to be absolutely groundbreaking, answering the prayers of millions.

It really is a follow-up to what we did in this body with the 21st Century Cures with the UPTON and DEGETTE effort that passed our committee 53–0, then passed here on the House floor 392–26.

There has been a lot of debate on where ARPA–H is going to be housed.

Should it be in NIH?

Should it be in HHS or someplace else?

Wherever this entity is finally located, we need to make sure that it is lean, that it is independent and nimble, and that there are the appropriate guardrails to keep other agencies from mission creep and siphoning that funding. The legislation that was introduced did a very good job of that and I am pleased to see that these protections were strengthened in the final product that we are going to be voting on this afternoon.

My partner in 21st Century Cures, DIANA DEGETTE, and really everybody on our committee were happy to include language for ARPA–H in our Cures 2.0 bill that we introduced more than a year ago. We thought that it was a great follow-up to the work that we did to enhance basic research on the first Cures bill which added $45 billion—paid for—in additional health research.

Funding for the NIH and the FDA included many important things such as the Cancer Moonshot and the Brain Initiative.

We are still in a pandemic. We have awful diseases that need cures, whether it be cancer, Alzheimer's, lupus, or diabetes that strike literally every single family.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. GUTHRIE. Mr. Speaker, I yield the gentleman from Michigan an additional 1 minute.

Mr. UPTON. This bill, ARPA–H, can provide the breakthroughs necessary to find cures for those diseases. The President has already signed $1 billion for this program into law. So what we need now is bipartisan authorization to complete the work. This bill certainly accomplishes that goal.

Mr. Speaker, I urge all of my colleagues, like we did before, to vote for this bill a little bit later this afternoon. Again, I just want to commend our great staff. As our leader, Congresswoman RODGERS, said: We have the best staff there is.

Is there any objection to that?

Hearing none—sorry, Ways and Means; sorry appropriators.

We do. We are the Energy and Commerce Committee, and we are going to find a cure for these diseases. This bill is a step in that direction.

Mr. GUTHRIE. Mr. Speaker, I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I must say that for many years we had a Congressman Brown on the committee who contributed a lot, particularly on healthcare issues. He chaired the Health Subcommittee. So it is an honor to hear from Ms. BROWN of Ohio. We have another Congresswoman BROWN from Ohio.

Mr. Speaker, I yield 3 minutes to the gentlewoman from Ohio (Ms. BROWN).

Ms. BROWN of Ohio. Mr. Speaker, I thank Chairman PALLONE for yielding, and I thank Congresswoman ESHOO for her leadership on this bill.

I applaud President Biden for having the foresight to propose the creation of an Advanced Research Projects Agency for Health, also known as ARPA–H, an agency tasked with driving breakthroughs in cancer, diabetes, Alzheimer's, and other difficult diseases.

The new science moonshot agency is modeled on the successes of the Defense Advanced Research Projects Agency, also known as DARPA. For decades DARPA has driven advances in technologies that have changed our lives for the better. Yet, there are so many things that we take for granted, things like the internet and flat-screen displays. I am confident the same will be true for ARPA–H as it seeks to accelerate advancements in health and medicine. Thanks to President Biden's leadership, my colleagues in Congress funded ARPA–H in March for the current fiscal year.

Yet in order to successfully carry out its mission, ARPA–H needs long-term resources and authorities. That is exactly what this bill does. The ARPA–H legislation would authorize the agency for 5 years and create the structure it needs to successfully drive breakthroughs that would otherwise die in the commercial market.

Yet ARPA–H not only needs long-term funding but also a long-term home. ARPA–H's mission is centered around high-risk, high-reward research, which is a charge that Cleveland has historically proven it is prepared to lead. With world-class healthcare systems, top-tier institutions of higher education, advanced biomedical companies, and a highly skilled manufacturing workforce, Cleveland has a long track record of bringing cutting-edge innovations from discovery all the way to production. This includes groundbreaking medical advancements like the first face transplant in America as well as the region's cutting-edge cancer research.

Now, wherever the agency lands, it will have a meaningful impact on the lives of Americans nationwide for generations to come. Creating ARPA–H with 1 year of funding was a good first step, but it is time to put this new breakthrough agency on firm footing

and in a firm location so we can truly start to revolutionize how we prevent, treat, and cure a range of diseases.

Mr. Speaker, I thank Chairman PALLONE again for his leadership, and I urge my colleagues to support the bill.

Mr. GUTHRIE. Mr. Speaker, I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentleman from Massachusetts (Mr. AUCHINCLOSS), who is also very much involved in healthcare issues with regard to the pharmaceutical industry and so many other health issues.

Mr. AUCHINCLOSS. Mr. Speaker, I strongly support Chairwoman ESHOO's bill to create an Advanced Research Projects Agency. This bill will ensure that ARPA–H can address the limitations of commercial markets and tackle high-risk, high-reward biomedical research in oncology, neuroscience, diabetes, artificial intelligence, mRNA and RNA, cell and gene therapy, and so much more.

As the global epicenter of breakthrough science, Massachusetts is a top candidate to host the headquarters of ARPA–H. Not only are we home to the highest proportion of top-ranked research universities in the world, but we also have the best and brightest in industry, healthcare, and academia.

We have also invested in infrastructure to support the needs of ARPA–H. Over the past decade, we have delivered 21.6 million square feet of lab space, in addition to over 100 incubators, accelerators, and co-working spaces.

This bill specifically directs ARPA–H to advance early disease detection, translational research, and health technologies. It realizes President Biden's goal of driving breakthroughs in cancer, Alzheimer's, diabetes, and infectious disease. From pre-competitive Alzheimer's research at the Massachusetts General Hospital to Vertex's work to utilize stem cell therapies to treat diabetes, we are aligned with and deeply committed to ARPA–H's goal in the Commonwealth.

I am proud to represent a State that is deeply invested in the success of ARPA–H.

Mr. Speaker, I urge my colleagues to support this legislation.

Mr. GUTHRIE. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, it is important we are here today.

I thank the chair of the other subcommittee whom I have the privilege to work alongside as the Republican leader. She has been a champion of ARPA–H as it first came out and at the first meeting at the White House. We have discussed quite a bit about where it should be and what the guardrails should be.

I know the funding got out in front of it. We all really wanted Congress to have a say in how this agency operated and not the executive branch the way, unfortunately, getting in front of authorization does.

I appreciate the hard work. I appreciate the work of the colleagues who have spoken and everybody else who is working on this together on our staff.

Mr. Speaker, I think it is important that we pass this bill. I urge my colleagues to vote for the bill tonight, and I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself the balance of my time to close.

Mr. Speaker, I just want to say in closing that I think you can feel the real enthusiasm and the hope that is involved with both the sponsors of this bill and those who spoke on both sides of the aisle.

We consider ourselves, the Energy and Commerce Committee, the innovation committee, and I think this is a prime example of the type of innovation that we see for the future and the hope in ARPA–H.

Mr. Speaker, I would ask for everyone on a bipartisan basis to vote for this, so we have a strong vote, and I yield back the balance of my time.

Mr. COLE. Mr. Speaker, I support H.R. 5585, the Advanced Research Projects Agency—Health Act. During my time in Congress, I have been a strong supporter of basic medical research, and I recognize the potential translational medical research holds when it builds off this prior research. The discoveries made by our scientists at NIH and at NIH-funded universities across the nation have the potential to transform the delivery of health care and the prevention, treatment, and ultimately curing of disease.

That support for research and its potential to transform the delivery of health care led me to be an initial supporter of ARPA–H. In collaboration with my colleagues on the Appropriations Committee, we provided ARPA–H with some initial funding in the Fiscal Year 2022 omnibus.

However, we are appropriators, not authorizers, and many of the basic decisions about the structure and functions of the agency had to be left unmade and instead be delegated to the Secretary of Health and Human Services. As I mentioned to him when he came before my subcommittee this spring, Congress still did not know how grants would be made or funded or how ARPA–H would interface with NIH.

I am pleased that this bill from the House Energy and Commerce Committee answers these questions and provides Congress the opportunity to shape this agency in line with our original intent. I am especially pleased that the resulting bill is fiscally responsible and will ensure proper oversight of ARPA–H as it implements this new research arm. H.R. 5585 establishes ARPA–H as an independent agency within HHS—separate from NIH—and provides its director with independence from NIH. It also establishes clear agency goals and mission and provides a framework for coordination to ensure ARPA–H's efforts will not duplicate or cannibalize the research efforts of other federal agencies, particularly NIH. Importantly, it also prohibits awards being made to foreign researchers and entities operating at behest of or in concert with our adversaries.

I urge my colleagues to support this legislation.

The SPEAKER pro tempore. All time for debate on the bill has expired.

AMENDMENT NO. 1 OFFERED BY MS. ESHOO OF CALIFORNIA

The SPEAKER pro tempore. It is now in order to consider amendment No. 1 printed in part C of House Report 117–381.

Ms. ESHOO. Mr. Speaker, I have an amendment at the desk made in order under the rule.

The SPEAKER pro tempore. The Clerk will designate the amendment.

The text of the amendment is as follows:

Page 3, line 13, strike ''There is established'' and insert the following:

(1) IN GENERAL.—There is established

Page 3, after line 23, insert the following:

(2) ORGANIZATION.—

(A) IN GENERAL.—There shall be within ARPA–H—

(i) an Office of the Director;

(ii) not more than 6 program offices; and

(iii) such special project offices as the Director may establish.

(B) PROGRAM OFFICES DEDICATED TO RESEARCH AND DEVELOPMENT.—Not fewer than two-thirds of the program offices of ARPA–H shall be exclusively dedicated to research and development.

Page 6, line 16, strike ''with the advice and consent of the Senate,''.

Page 14, strike line 19, and all that follows through page 16, line 6, and insert the following:

''(3) UTILIZATION OF LEASE FUNDS.—The Director shall deposit amounts of cash consideration received for a lease entered into under this subsection in the 'Advanced Research Projects Agency for Health' account as discretionary offsetting collections, and such amounts shall be available only to the extent and in the amounts provided in advance in appropriations Acts—

''(A) to cover the full costs to ARPA–H in connection with the lease;

''(B) for maintenance, capital revitalization, and improvements of the real property assets and related personal property under the jurisdiction of the Director; and

''(C) for maintenance, capital revitalization, and improvements of the real property assets and related personal property at the respective center or facility of ARPA–H engaged in the lease, subject to the concurrence of the Director.''.

Page 26, lines 15 through 19, amend paragraph (3) to read as follows:

''(3) not award any grants, cooperative agreements, contracts, prizes, and other transactions to nondomestic recipients organized under the laws of a covered foreign country (as defined in section 119C of the National Security Act of 1947); and

Page 34, lines 23 and 24, strike ''There is authorized'' and insert the following:

(1) IN GENERAL.—To carry out this section, there is authorized

Page 35, after line 2 (but before the close quotation mark and second period) insert the following:

(2) ADMINISTRATIVE EXPENSES.—Not more than 15 percent of the amounts made available to carry out this section for any fiscal year may be used for administrative expenses to operate ARPA–H.

The SPEAKER pro tempore. Pursuant to House Resolution 1191, the gentlewoman from California (Ms. ESHOO) and a Member opposed each will control 5 minutes.

The Chair recognizes the gentlewoman from California.

□ 1645

Ms. ESHOO. Mr. Speaker, I yield myself such time as I may consume.

I offer this bipartisan manager's amendment to improve and strengthen

the bill. I thank my Republican colleagues on the Health Subcommittee, including Ranking Member MCMORRIS RODGERS, Ranking Member GUTHRIE, and Dr. BURGESS for working closely with me on this bill over the last several weeks.

This manager's amendment makes sure that the structure of ARPA–H will help the Agency achieve success. Specifically, the amendment requires: First, two-thirds of the ARPA–H program offices be exclusively dedicated to research and development; number two, not more than 15 percent of the ARPA–H budget to be used on administrative expenses; and, thirdly, removes the requirement of Senate confirmation of the ARPA–H director.

I think these are commonsense provisions that improve the bill and, ultimately, strengthen ARPA–H and its mission; and it is why I urge my colleagues to support this amendment.

Mr. Speaker, I yield back the balance of my time.

Mr. GUTHRIE. Mr. Speaker, I claim the time in opposition, even though I am not opposed to the bill.

The SPEAKER pro tempore. Without objection, the gentleman from Kentucky is recognized for 5 minutes.

There was no objection.

Mr. GUTHRIE. Mr. Speaker, the Chair of the subcommittee kind of went through what the amendment says. Another thing that we need to make sure is reinforced is that the amendment would ensure that agency and precious U.S. taxpayer dollars can never go to nondomestic recipients organized under the laws of a covered foreign entity as defined by the National Security Act of 1947. This includes China, Russia, Iran, and North Korea. So I want to make sure we understand that.

I said this on the debate on the bill that the Chair and I were talking back and forth. And I understood the mission of what we wanted to accomplish with ARPA–H, but I was concerned about the application of it and how it would actually be put into place. We had a lot of discussions based on that.

This amendment really does define as best as we can define in legislation, without vague terms, what we want ARPA–H to do. This amendment ensures that 85 percent of the money goes to research and not to administration and growing an agency. We think that this really does narrow and, as we said earlier, put guardrails. This amendment is what accomplishes that with the bill. I am for this amendment, and I encourage its adoption.

Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. Pursuant to the rule, the previous question is ordered on the bill and the amendment offered by the gentlewoman from California (Ms. ESHOO).

The question is on the amendment offered by the gentlewoman from California (Ms. ESHOO).

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mrs. BOEBERT. Mr. Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this question are postponed.

Pursuant to clause 1(c) of rule XIX, further consideration of H.R. 5585 is postponed.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Proceedings will resume on questions previously postponed. Votes will be taken in the following order:

The following questions on H.R. 7666:

En bloc amendments No. 1;

En bloc amendments No. 2;

Amendment No. 4 by Mrs. DEMINGS of Florida;

Amendment No. 6 by Mrs. RODGERS of Washington;

Amendment No. 8 by Mr. GRIFFITH of Virginia;

Motion to recommit, if offered;

Passage of the bill, if ordered;

The following questions on H.R. 5585:

Amendment No. 1 by Ms. ESHOO of California;

Motion to recommit, if offered;

Passage of the bill, if ordered; and

The motion to suspend the rules and pass H.R. 6538.

The first electronic vote will be conducted as a 15-minute vote. Pursuant to clause 9 of rule XX, remaining electronic votes will be conducted as 5-minute votes.

RESTORING HOPE FOR MENTAL HEALTH AND WELL-BEING ACT OF 2022

The SPEAKER pro tempore. Pursuant to clause 1(c) of rule XIX, further consideration of the bill (H.R. 7666) to amend the Public Health Service Act to reauthorize certain programs relating to mental health and substance use disorders, and for other purposes will now resume.

The Clerk read the title of the bill.

AMENDMENTS EN BLOC NO. 1 OFFERED BY MR. PALLONE OF NEW JERSEY

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the unfinished business is the question on amendments en bloc No. 1, printed in part E of House Report 117–381, on which further proceedings were postponed and on which the yeas and nays were ordered.

The Clerk will redesignate the amendments en bloc.

The Clerk redesignated the amendments en bloc.

The SPEAKER pro tempore. The question is on the amendments en bloc offered by the gentleman from New Jersey (Mr. PALLONE).

The vote was taken by electronic device, and there were—yeas 387, nays 32, not voting 10, as follows:

[Roll No. 281]

YEAS—387

Adams
Aderholt
Aguilar
Allen
Allred
Amodei
Armstrong
Arrington
Auchincloss
Axne
Babin
Bacon
Baird
Balderson
Barr
Barragán
Bass
Beatty
Bentz
Bera
Bergman
Beyer
Bice (OK)
Bilirakis
Bishop (GA)
Blumenauer
Blunt Rochester
Bonamici
Bost
Bourdeaux
Bowman
Boyle, Brendan F.
Brady
Brown (MD)
Brown (OH)
Brownley
Buchanan
Bucshon
Budd
Burgess
Bush
Bustos
Butterfield
Calvert
Cammack
Carbajal
Cárdenas
Carey
Carl
Carson
Carter (GA)
Carter (LA)
Carter (TX)
Cartwright
Case
Casten
Castor (FL)
Castro (TX)
Cawthorn
Chabot
Cheney
Cherfilus-McCormick
Chu
Cicilline
Clark (MA)
Clarke (NY)
Cleaver
Clyburn
Cohen
Cole
Comer
Connolly
Cooper
Correa
Costa
Courtney
Craig
Crawford
Crenshaw
Crist
Crow
Cuellar
Curtis
Davids (KS)
Davis, Danny K.
Davis, Rodney
Dean
DeFazio
DeGette
DeLauro
DelBene
Demings
DeSaulnier
DesJarlais
Deutch
Diaz-Balart
Dingell
Doggett
Doyle, Michael F.
Duncan
Dunn
Ellzey
Emmer
Escobar
Eshoo
Espaillat
Estes
Evans
Feenstra
Ferguson
Fischbach
Fitzgerald
Fitzpatrick
Fleischmann
Fletcher
Flores
Foster
Frankel, Lois
Franklin, C. Scott
Fulcher
Gallagher
Gallego
Garamendi
Garbarino
Garcia (CA)
García (IL)
Garcia (TX)
Gibbs
Gimenez
Gohmert
Golden
Gomez
Gonzales, Tony
Gonzalez (OH)
Gonzalez, Vicente
Gottheimer
Granger
Graves (LA)
Graves (MO)
Green (TN)
Green, Al (TX)
Griffith
Grijalva
Grothman
Guest
Guthrie
Harder (CA)
Harris
Harshbarger
Hartzler
Hayes
Hern
Herrell
Herrera Beutler
Higgins (LA)
Higgins (NY)
Himes
Hinson
Hollingsworth
Horsford
Houlahan
Hoyer
Hudson
Huffman
Huizenga
Issa
Jackson
Jackson Lee
Jacobs (CA)
Jacobs (NY)
Jayapal
Jeffries
Johnson (GA)
Johnson (LA)
Johnson (OH)
Johnson (SD)
Johnson (TX)
Jones
Joyce (OH)
Joyce (PA)
Kahele
Kaptur
Katko
Keating
Keller
Kelly (IL)
Kelly (MS)
Kelly (PA)
Khanna
Kildee
Kilmer
Kim (CA)
Kim (NJ)
Kind
Kinzinger
Kirkpatrick
Krishnamoorthi
Kuster
Kustoff
LaHood
LaMalfa
Lamb
Lamborn
Langevin
Larsen (WA)
Larson (CT)
Latta
LaTurner
Lawrence
Lawson (FL)
Lee (CA)
Lee (NV)
Leger Fernandez
Lesko
Letlow
Levin (CA)
Levin (MI)
Lieu
Lofgren
Long
Lowenthal
Lucas
Luetkemeyer
Luria
Lynch
Mace
Malinowski
Malliotakis
Maloney, Carolyn B.
Maloney, Sean
Mann
Manning
Matsui
McBath
McCarthy
McCaul
McClain
McCollum
McEachin
McGovern
McHenry
McKinley
McNerney
Meeks
Meijer
Meng
Meuser
Mfume
Miller (WV)
Miller-Meeks
Moolenaar
Mooney
Moore (UT)
Moore (WI)
Morelle
Moulton
Mrvan
Mullin
Murphy (FL)
Murphy (NC)
Nadler
Napolitano
Neal
Neguse
Newhouse
Newman
O'Halleran
Obernolte
Ocasio-Cortez
Omar
Owens
Palazzo
Pallone
Palmer
Panetta
Pappas
Pascrell
Payne
Perlmutter
Pfluger
Phillips
Pingree